

WHAT IS CLAIMED IS:

1. A rotational medical device, comprising:  
an elongate flexible tubular body, having a proximal end and a distal  
end;  
5 a rotatable element extending through the body;  
a rotatable cutter at the distal end of the body and connected to the  
rotatable element;  
a control on the proximal end of the body; and  
a sensor on the device in electrical communication with an indicator, for  
10 indicating resistance to rotation of either the rotatable element or rotatable cutter.
2. A rotational medical device as in Claim 1, wherein the indicator  
comprises a source of tactile feedback.
3. A rotational medical device as in Claim 1, wherein the indicator  
comprises at least one light.
- 15 4. A rotational medical device as in Claim 1 further comprising a  
reverse direction control such that the rotatable cutter can be rotating in either of two  
directions.
5. A rotational medical device as in Claim 1, wherein the rotatable  
cutter comprises a generally helical thread.
- 20 6. A rotational medical device as in Claim 1, wherein the rotatable tip is  
positioned entirely inside of the tubular body.
7. A rotational medical device as in Claim 1, further comprising an  
annular space between the rotatable tip and an interior wall of the tubular body.
8. A rotational medical device as in Claim 1, wherein the control unit is  
25 attached to the proximal end of the body by a rotatable hub.
9. A rotational medical device as in Claim 1, further comprising a  
reinforcing sleeve over at least a portion of the proximal end of the body.
10. A rotatable medical device as in Claim 1, wherein the rotatable  
element and the cutter can translate relative to the body.

11. A method of removing material from a vessel, comprising the steps  
of:

providing an elongate, flexible, tubular body, having a proximal end and  
a distal end, a rotatable cutter at the distal end of the tubular body, and a control  
on the proximal end of the tubular body;

transluminally advancing the distal end of the tubular body to the  
material;

rotating the rotatable cutter;

drawing portions of the material proximally past the rotatable cutter and  
into the tubular body; and

providing feedback to the operator in response to changes in the load on  
the rotatable cutter.

12. A method as in Claim 11, wherein the drawing step is accomplished  
by connecting a vacuum source to the proximal end of the tubular body.

13. A method as in Claim 11, wherein the advancing step is  
accomplished by applying axial distal pressure on the tubular body, and further  
comprising the step of reducing the amount of axial distal pressure in response to  
feedback indicating a change in the load on the rotatable cutter.

14. A method as in Claim 12, wherein the control both activates the  
vacuum and commences rotation of the rotatable cutter.

15. A method of removing material from a vessel, comprising the steps  
of:

providing an elongate, flexible, tubular body, having a proximal end and  
a distal end, a rotatable cutter proximate the distal end of the tubular body, and a  
control on the proximal end of the tubular body for controlling the rotatable  
cutter;

advancing the distal end of the tubular body transluminally to the  
material;

applying a vacuum through the tubular body;

rotating the rotatable cutter after applying the vacuum;

drawing portions of the material proximally past the rotatable cutter and into the tubular body; and

providing feedback to the operator in response to changes in the load on the rotatable cutter.

5           16.           The method of Claim 15, wherein the operator can reverse the rotation of the rotatable cutter.

17.           The method of Claim 16, wherein the rotation of the rotatable cutter is reversed by the operator when the operator receives feedback indicating an overload condition.

10           18.           A rotatable cutter for use in an elongate flexible tubular catheter for removing material from a vessel, comprising:

a cutter shaft having a proximal end and a distal end and a longitudinal axis of rotation extending therebetween;

a generally helical thread on at least a distal portion of the shaft; and

15           at least one radially outwardly extending flange on the proximal end of the shaft.

19.           A rotatable tip as in Claim 18, further comprising a central guidewire lumen extending from the proximal end to the distal end of the cutter shaft, along the axis of rotation.

20           20.           A rotatable cutter as in Claim 18, wherein the flange has a beveled leading edge.

21.           A rotational medical device, comprising:

an elongate flexible tubular body, having a proximal end and a distal end;

25           a rotatable element extending through and spaced radially inwardly from the body;

an aspiration lumen extending through the tubular body in between an interior wall of the elongate flexible tubular body and exterior wall of the rotatable element;

a rotatable cutter at the distal end of the body, connected to the rotatable element; and

a control on the proximal end of the body;

wherein the tubular body has a first cross-sectional area, and the aspiration lumen has a second cross-sectional area, and the cross-sectional area of the aspiration lumen is at least about 35% of the cross-sectional area of the tubular body.

22. A method of removing material from a patient, comprising the steps of:

providing an elongate flexible tubular body, having a proximal end and a distal end, a rotatable cutter on the distal end of the tubular body, and a control on the proximal end of the tubular body;

advancing the distal end of the tubular body to the material to be removed;

manipulating the control to activate a vacuum through the tubular body; and

manipulating the control to commence rotation of the rotatable cutter to remove material from the patient.

23. A method as in Claim 22, wherein rotation of the cutter can only be accomplished if the vacuum is on.

24. A method as in Claim 22, wherein said advancing step comprises advancing the distal end of the tubular body transluminally through a vessel to the material to be removed.

25. A method as in Claim 24, wherein the advancing step comprises advancing the tubular body along a guidewire.

26. A method as in Claim 22, wherein the advancing step comprises advancing the tubular body through a percutaneous access device.

27. A method as in Claim 22, further comprising the step of infusing fluid through a guidewire flush port on the proximal control.

28. A method as in Claim 22, further comprising providing feedback regarding a sensed vacuum operational condition.

29. A rotational medical device, comprising:

an elongate flexible tubular body, having a proximal end and a distal end;

a rotatable element extending through the body;

a rotatable cutter at the distal end of the body and connected to the rotatable element;

a control on the proximal end of the body; and

an axially extending aspiration channel between the rotatable element and the tubular body.

30. A rotational medical device as in Claim 29, further comprising an indicator for indicating changes in flow through the aspiration channel.

31. A rotational medical device as in Claim 29, wherein the control is mounted on a handle configured for one hand operation of the rotational medical device, and the control activates both rotation of the rotatable cutter and an application of a vacuum.

32. A rotational medical device as in Claim 31, wherein the control is activatable by single finger operation, and, upon actuation thereof, initiates the application of the vacuum within the tubular body before initiating rotation of the rotatable tip.

33. A rotational medical device as in Claim 32, further comprising a shipping lock-out wire adapted to hold the control in a vacuum activated position and rotation deactivated position.

34. A rotational medical device as in Claim 29, wherein the handle further comprises an infusion port, and a proximal guidewire port.

35. A rotational atherectomy and aspiration catheter, for removing obstruction from a body vessel comprising:

an elongate flexible tubular body, having a proximal end and a distal end and at least one lumen extending axially therethrough;

a rotatable core extending through the lumen;  
a helical cutter on a distal end of the rotatable core;  
a vacuum source coupled to the proximal end of the tubular body; and  
a control for activating the vacuum source when the core is rotated.

5           36.       A method of removing an obstruction from a body vessel comprising  
the steps of:

                  positioning a rotational atherectomy catheter at a treatment site in a body  
                  lumen;

                  rotating a rotatable cutter on the rotational atherectomy catheter, to  
10               dislodge material in the body lumen; and

                  applying a vacuum to the rotational atherectomy catheter to proximally  
                  withdraw material dislodged by the rotatable cutter;

                  wherein the step of rotating the rotatable cutter is only performed after a  
                  predetermined level of vacuum is established.

15           37.       The method of Claim 36 further comprising disabling the rotation of  
the rotatable cutter if the actual level of vacuum falls below the predetermined level.

                  38.       The method of Claim 31 further comprising activating a low vacuum  
                  level alarm to alert a user to a low vacuum condition.

                  39.       The method of Claim 37, wherein the actual level of vacuum is  
20               sensed by a flow detector.

                  40.       The method of Claim 37, where the actual level of vacuum is sensed  
                  by a pressure transducer.

                  41.       A rotational medical device comprising an elongate tubular member,  
a housing secured to a distal end of the elongate tubular member, a cutter at least  
25               partially encased by the housing and connected to a drive member, the drive member  
extending through the elongate tubular member, wherein the cutter and the housing are  
configured to retain the cutter tip at least partially within the housing should the cutter  
separate from the drive member.

42. The rotational medical device of Claim 41, wherein the cutter tip comprises at least two outwardly extending radial flanges which are received by an annular race within the housing.

43. The rotational medical device of Claim 42, wherein the annular race is positioned near the proximal extremity of the housing.

44. The rotational medical device of Claim 42, wherein the cutter tip is snap fit to the cutter housing.

45. The rotational medical device of Claim 42, wherein the housing further comprises at least one inwardly extending stationary member which is cooperable with the flanges to shear material passing thereby.

46. The rotational medical device of Claim 41, wherein the cutter has an annular race and the housing has at least two inwardly extending radial retainer members which are received by the annular race.

47. The rotational medical device of Claim 46, wherein the cutter is snap fit to the cutter housing.

48. The rotational medical device of Claim 41, wherein the cutter has an end cap.

49. The rotational medical device of Claim 41, wherein a distal end of the cutter is rounded to reduce trauma to a vasculature of a patient during insertion into the patient.

50. The rotational medical device of Claim 41, wherein the cutter has at least one external helical flange.

51. The rotational medical device of Claim 50, wherein the helical flange has a blunt leading edge.

52. The rotational medical device of Claim 50, wherein the helical flange tapers toward a distal end of the cutter.

53. The rotational medical device of Claim 41, wherein the housing has a blunt distal end.

54. The rotational medical device of Claim 41, wherein the housing is comprised of two portions which are attached together to capture the cutter.

55. The rotational medical device of Claim 54, wherein the two portions are laser-welded together.

56. The rotational medical device of Claim 55, wherein the two portions comprise a distal portion and a proximal portion.

5 57. A rotational medical device, comprising:  
an elongate flexible tubular body, having a proximal end and a distal end;  
a rotatable element extending through the body;  
a rotatable cutter at the distal end of the body and connected to the  
10 rotatable element;  
an aspiration lumen extending through the tubular body for permitting a flow of material in the proximal direction; and  
an indicator for indicating changes in flow through the aspiration lumen.

15 58. A rotational medical device as in Claim 57, wherein the indicator comprises a source of tactile feedback.

59. A rotational medical device as in Claim 57, wherein the indicator comprises at least one light.

60. A rotational medical device, comprising:  
an elongate flexible tubular body, having a proximal end and a distal  
20 end;  
a rotatable element extending through the body;  
a rotatable cutter at the distal end of the body and connected a motor through the rotatable element;  
a control on the proximal end of the body; and  
25 a sensor on the device in electrical communication with a motor control circuit, wherein the motor control circuit is capable of receiving a signal from the sensor for indicating an operating condition based upon resistance to rotation of either the rotatable element or rotatable cutter and wherein the motor control circuit capable of disengaging the motor rotation from the cutter in the event the  
30 operating condition indicates an overload condition.



61. A rotational medical device as in Claim 60 further comprising at least one indicator for indicating the operating condition.

62. A rotational medical device as in Claim 61, wherein the indicator includes a visual indicator.

5 63. A rotational medical device as in Claim 61, wherein the indicator includes an auditory indicator.

64. A rotational medical device as in Claim 61, wherein the indicator includes a tactile indicator.

10 65. A rotational medical device comprising an elongated tubular body, a cutter disposed at a distal end of the tubular body, the cutter rotatable relative to the tubular body, a control disposed at the proximal end of the tubular body, the control including a connecting hub, the connecting hub coupling the tubular body to the control such that the tubular body may rotate relative to the control.

15 66. A rotational medical device as in Claim 65 further comprising a motor housed within the control and a flexible drive element transmitting power from the motor to the cutter, wherein the flexible drive element extends through the hub such that the flexible drive element may rotate relative to the hub and tubular body while still allowing the tubular body and hub to rotate relative to the control.

20 67. A rotational medical device as in Claim 66 further comprising a drive coupling, the drive coupling comprising a sleeve and a plate which slides within the sleeve and engages the sleeve to transmit rotation between the sleeve and the plate, wherein at least one of the sleeve and plate shields the motor from fluids which may leak into the control.

25 68. A rotational medical device comprising a cutter, an elongated tubular body connecting the cutter to a control, the control having a drive motor, the drive motor transmitting rotation to the cutter through at least a flexible drive shaft, the cutter capable of axial displacement relative to the control.

69. A rotational medical device as in Claim 68, wherein the cutter is capable of axial displacement relative to the motor.

70. A rotational medical device as in Claim 68 further comprising as a transfer shaft that extends through the motor and that is coupled to an output of the motor such that the transfer shaft is capable of axial displacement relative to the motor.

5 71. A rotational medical device as in Claim 68, further comprising a transfer shaft that transfers rotation from the motor to the flexible drive shaft and wherein the flexible drive shaft is capable of axial displacement relative to the transfer shaft.

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